

# Criteria-Based Consultation Prescribing Program

## CRITERIA FOR DRUG COVERAGE

### Nemolizumab-ilto (Nemluvio)

#### Notes:

- Quantity Limits: Yes
- ^Adequate trial is defined as the following:
  - Topical corticosteroids – 8 weeks
  - Topical calcineurin inhibitors – 6 weeks
  - Phototherapy – 8 weeks
  - Atopic dermatitis systemic medications – 6 weeks
  - Biologic medications – 12 weeks
- \* Intolerance excludes adverse drug reactions that are expected, mild in nature, resolve with continued treatment, and do not require medication discontinuation

**Initiation (new start) criteria:** Non-formulary **nemolizumab-ilto (Nemluvio)** will be covered on the prescription drug benefit for 12 months when the following criteria are met:

1. Prescriber is a dermatologist and patient has a diagnosis of moderate to severe atopic dermatitis
  - Patient is 12 years of age or older
  - Patient has tried and failed an adequate trial<sup>^</sup> of, or patient has an allergy or intolerance to the following medications:
    - At least 1 medium to super-potent/ultrahigh potency topical corticosteroid
    - At least 1 topical calcineurin inhibitor
  - Patient has tried and failed narrow-band ultraviolet B (NB-UVB) phototherapy (unless documented by prescriber phototherapy not appropriate)
  - Patient has tried and failed an adequate trial<sup>^</sup> of, or patient has an allergy or intolerance to at least 1 of the following systemic medications (or contraindication to all):
    - Azathioprine
    - Cyclosporine
    - Methotrexate
    - Mycophenolate
  - Patient has tried and failed an adequate trial<sup>^</sup> of, or patient has an allergy or intolerance to all the following medications:
    - Tralokinumab-ldrm (Adbry) (criteria based)
    - Dupilumab (Dupixent) (criteria based)
  - Patient is NOT currently taking dupilumab (Dupixent), mepolizumab (Nucala), reslizumab (Cinqair), benralizumab (Fasenra), tezepelumab-ekko (Tezspire), omalizumab (Xolair), tralokinumab-ldrm (Adbry) or lebrikizumab-lbkz (Ebglyss)
  - Patient is NOT currently on a Janus kinase inhibitor (oral or topical) for atopic dermatitis

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2. Prescriber is a dermatologist and patient has a diagnosis of prurigo nodularis
  - Patient is at least 18 years old
  - Patient has tried and failed an adequate trial<sup>^</sup> of, or patient has an allergy or intolerance to the following medications
    - At least 1 high potency (Class 2) or super-potent/ultrahigh potency (Class 1) topical corticosteroid
    - At least 1 of the following: Methotrexate, cyclosporine, or azathioprine
    - At least 1 gabapentinoid (gabapentin or pregabalin)
    - At least 1 antidepressant
    - Dupilumab (Dupixent) (criteria based)
  - Patient has tried and failed an adequate trial<sup>^</sup> of phototherapy (unless documented by prescriber phototherapy not appropriate)
  - Patient is NOT currently taking mepolizumab (Nucala), reslizumab (Cinqair), benralizumab (Fasenra), tezepelumab-ekko (Tezspire), omalizumab (Xolair), dupilumab (Dupixent), tralokinumab-ldrm (Adbry) or lebrikizumab-lbkz (Ebglyss)

**Criteria for new members entering Kaiser Permanente already taking the medication who have not been reviewed previously:** Non-formulary nemolizumab-ilto (Nemluvio) will be covered on the prescription drug benefit for 12 months when the following criteria are met:

1. Prescriber is a dermatologist and patient has a diagnosis of moderate to severe atopic dermatitis
  - Patient is 12 years of age or older
  - Patient has tried and failed, or patient has an allergy or intolerance, to the following medications OR documentation from dermatologist that these medications are not appropriate based on patient's disease severity
    - At least 1 medium to super-potent/ultrahigh potency topical corticosteroid
    - At least 1 topical calcineurin inhibitor\*
  - Patient has tried and failed narrowband ultraviolet B (NB-UVB) phototherapy (unless documented by prescriber phototherapy not appropriate)
  - Patient has tried and failed, or patient has an allergy or intolerance, to at least 1 of the following systemic medications (or contraindication to all) OR documentation from dermatologist that these medications are not appropriate based on patient's disease severity
    - Azathioprine

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### Nemolizumab-ilto (Nemluvio)

- Cyclosporine
    - Methotrexate
    - Mycophenolate
  - Patient has tried and failed an adequate trial^ of, or patient has an allergy or intolerance to all the following medications:
    - Tralokinumab-ldrm (Adbry) (criteria based)
    - Dupilumab (Dupixent) (criteria based)
  - Patient is NOT currently taking mepolizumab (Nucala), reslizumab (Cinqair), benralizumab (Fasenra), tezepelumab-ekko (Tezspire), omalizumab (Xolair), dupilumab (Dupixent), tralokinumab-ldrm (Adbry) or lebrikizumab-lbkz (Ebglyss)
  - Patient is NOT currently on a Janus kinase inhibitor (oral or topical) for atopic dermatitis
2. Prescriber is a dermatologist and patient has a diagnosis of prurigo nodularis
- Patient is at least 18 years old
  - Patient has tried and failed an adequate trial^ of, or patient has an allergy or intolerance to the following medications
    - At least 1 high potency or super-potent/ultrahigh potency topical corticosteroid
    - At least 1 of the following: Methotrexate, cyclosporine, or azathioprine
    - At least 1 gabapentinoid (gabapentin or pregabalin)
    - At least 1 antidepressant
    - Dupilumab (Dupixent) (criteria based)
  - Patient has tried and failed an adequate trial^ of phototherapy (unless documented by prescriber phototherapy not appropriate)
  - Patient is NOT currently taking mepolizumab (Nucala), reslizumab (Cinqair), benralizumab (Fasenra), tezepelumab-ekko (Tezspire), omalizumab (Xolair), dupilumab (Dupixent), tralokinumab-ldrm (Adbry) or lebrikizumab-lbkz (Ebglyss)

**Continued use criteria for patients previously approved per the above criteria who are currently stable on the medication:** Non-formulary **nemolizumab-ilto (Nemluvio)** will continue to be covered on the prescription drug benefit for 12 months when the following criteria are met:

1. Prescriber is a dermatologist and patient has a diagnosis of moderate to severe atopic dermatitis

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- Patient has responded to nemolizumab-ilto treatment as determined by prescriber
  - Patient is NOT currently taking dupilumab (Dupixent), mepolizumab (Nucala), reslizumab (Cinqair), benralizumab (Fasenra), tezepelumab-ekko (Tezspire), omalizumab (Xolair), tralokinumab-ldrm (Adbry) or lebrikizumab-lbkz (Ebglyss)
  - Patient is NOT currently on a Janus kinase inhibitor (oral or topical) for atopic dermatitis
2. Prescriber is a dermatologist and patient has a diagnosis of prurigo nodularis
- Patient has responded to nemolizumab-ilto treatment as determined by prescriber
  - Patient is NOT currently taking mepolizumab (Nucala), reslizumab (Cinqair), benralizumab (Fasenra), tezepelumab-ekko (Tezspire), omalizumab (Xolair), dupilumab (Dupixent), tralokinumab-ldrm (Adbry) or lebrikizumab-lbkz (Ebglyss)